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10/027,715	12/20/2001	Robert Kraemer	J&J 2081	9750

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EXAMINER

BOGART, MICHAEL G

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/027,715

**Applicant(s)**

KRAEMER ET AL.

**Examiner**

Michael G. Bogart

**Art Unit**

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18-30,32-34,36-39 and 41-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26,27,30,33 and 34 is/are allowed.
- 6) ☒ Claim(s) 18,28,36-38 and 41-43 is/are rejected.
- 7) ☒ Claim(s) 19-25,29,32 and 39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Amendment*

Applicants' amendment pages 2-7 is referenced as Appl. No. 10/179,497 which is a different application. Page 1 of the amendment correctly references the instant invention.

### *Claim Objections*

Claim 23 is objected to because of the following informalities:

Claim 23 depends from canceled claim 16. For the purpose of examination against the prior art, claim 23 is interpreted as depending from claim 18 due to the context of the claims.

Appropriate correction is required.

### *Claim Rejections 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18, 28 and 43 are rejected under 35 U.S.C. § 102(e) as being anticipated by Johnson *et al.* (USPAP 2003/0093049 A1).

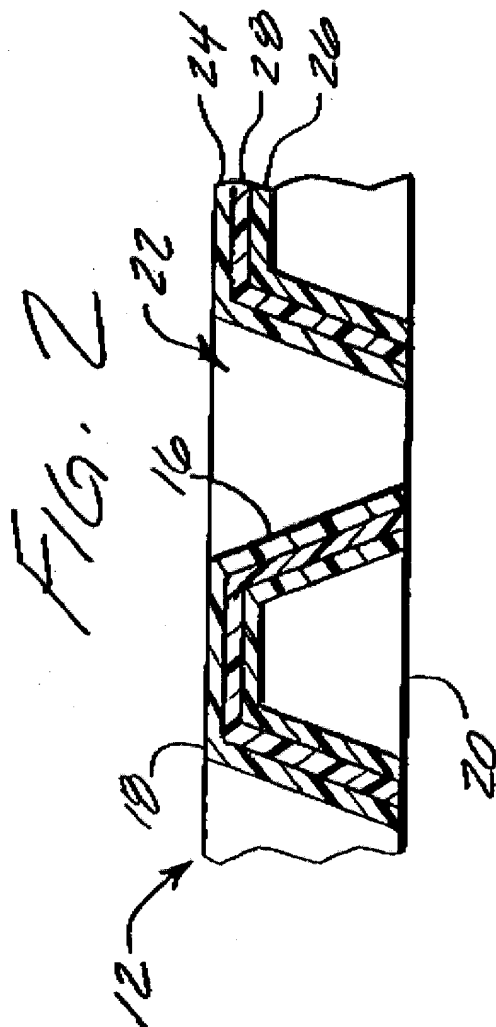
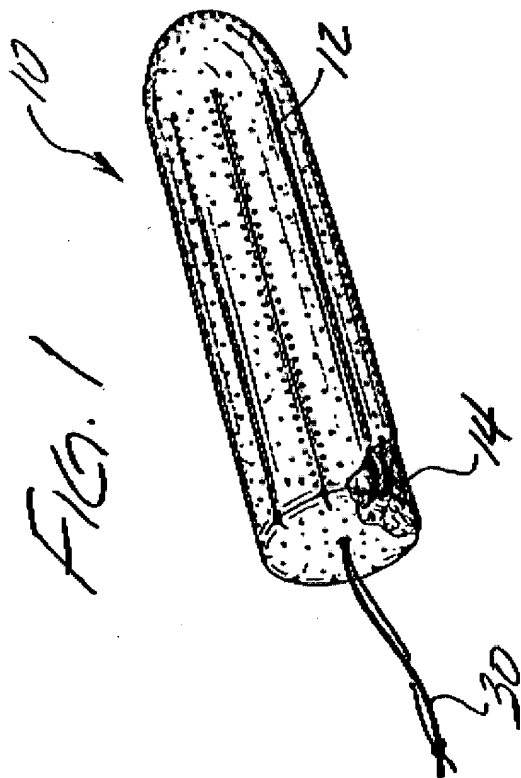
Regarding claim 18, Johnson *et al.* teach an intravaginal device (10) for feminine hygiene comprising a core (14) which is surrounded by a sheathing (12), wherein the sheathing (12)

Art Unit: 3761

comprises at least two separate layers of material (24, 26, 28) which at least partially lie one on top of the other and are bonded to one another (see figs. 1 and 2, below)(¶'s 0021-0036).

Regarding claim 28, Johnson *et al.* teach a sheathing (12) comprising three layers (24, 26, 28)(fig. 2).

Regarding claim 43, Johnson *et al.* teach that an insertion end of the device (10) is tapered conically (fig. 1).



***Claim Rejections -35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 36-38, 41 and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson *et al.* as applied to claims 18, 28 and 43 above, and further in view of Zunker *et al.* (US 6,090,098 A).

Johnson *et al.* teach the claimed invention except for the specific shape and size of the device.

Zunker *et al.* teach an intravaginal device (50) sized to provide support to a user's urinary system (col. 1, line 59-col. 2, line 22).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to selectively size the device of Johnson *et al.* in order for it to be of the appropriate size to aide in preventing urinary incontinence, as taught by Zunker *et al.*

Regarding claim 37, Johnson *et al.* teach that the device (10) is substantially cylindrical (fig. 1).

Regarding claim 38, Zunker *et al.* teach an intravaginal device (50) which is substantially ovoid (col. 6, lines 3-11).

Regarding claims 41 and 42, Zunker *et al.* teach a resilient member (58) which gives the disclosed device (50) its axial compressive resistance.

Johnson *et al.* and Zunker *et al.* teaches the claimed invention except for the specific value of it's axial compressive resistance of the device.

Generally, optimization of ranges alone is not sufficient to patentably distinguish an apparatus over the prior art. *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969), *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). MPEP § 2144.05 (II).

In the present case, increasing or decreasing the resilience of the member (58) taught by Zunker *et al.* will cause a directly corresponding increase or decrease in the amount of force required to axially compress the device (50). Axial compressibility of the device is therefor a result effective variable. At the time of the invention, it would have been obvious to one of

ordinary skill in the art to optimize the resiliency of the device of Zunker *et al.* in order to achieve a balance between comfort and the ability of the device to stay in place on a user.

***Allowable Subject Matter***

Claims 26, 27, 30, 33 and 34 are allowed.

Claims 19-25, 29, 32 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments filed 13 September 2004 have been fully considered but they are not persuasive.

Regarding claims 18 and 28, Applicants assert that Johnson *et al.* teach a sheath which is a plastic material which is a laminate having at least three layers. Applicants contend that the claimed separate bonded together layers of the instant invention are distinct from the referenced laminated multilayer construction. This argument is not persuasive because Johnson *et al.* teaches separate layers (24, 26, 28) having different properties (such as melting points, etc.) which have been bonded together into a laminate film (¶'s 0021-0036). The sheath of the presently claimed apparatus is in fact a laminate of component layers bonded together prior to construction of the device, to the extent that they may be interpreted as separate layers, then the layers of the reference may also be reasonably interpreted as "separate." Applicants have

Art Unit: 3761

claimed no additional limitations to distinguish the claimed multilayered sheath from the multilayered film of the reference.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (703) 605-1184. The examiner can normally be reached Monday-Friday.

In the event the examiner is not available, the examiner's supervisor, Larry Schwartz may be reached at phone number (703) 308-1412. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 746-3380 for informal communications.

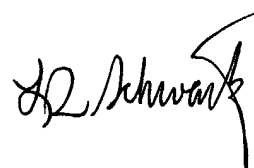


Art Unit: 3761

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-0858.



Michael Bogart  
21 September 2004



Larry I. Schwartz  
Supervisory Patent Examiner  
Group 3700